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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,837	04/10/2007	Heike Barlag	32860-001100/US	9815

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EXAMINER	
DIETERLE, JENNIFER M	

ART UNIT	PAPER NUMBER
1795	

NOTIFICATION DATE	DELIVERY MODE
09/17/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/587,837	BARLAG ET AL.	
	Examiner	Art Unit	
	Jennifer Dieterle	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *11-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 21-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 July 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/30/08, 8/16/07, 2/2/07, 7/28/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-28 are pending.

Claims 11-20 have been withdrawn.

Claims 1-10 and 21-28 are being examined.

Election/Restrictions

1. Claims 11-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group II, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/18/10.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Figure 9 should be carefully reviewed, there are numerous reference numbers that are not provided for in the specification, these include but are not limited too: 4a-c, 110, 20i, 11i (also in figure 11), u.sub.out, t, and 10i. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) (WITHOUIT THE ADDITION OF NEW MATER) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet

should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 1 and claims 2-10, 21-25 and 28, which depend from claim 1, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Case law holds that applicant's specification must be "commensurately enabling [regarding the scope of the claims]" *Ex parte Kung*, 17 USPQ2d 1545, 1547 (Bd. Pat. App. Inter. 1989) otherwise undue experimentation would be involved in determining how to practice and use applicant's invention. Although the statute itself does not use the phrase "undue experimentation", it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the

invention without undue experimentation as stated in *Ex parte Forman*, 230 USPQ 546, 547 (Bd. Pat. App. Inter. 1986) and in *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Specifically, in *In re Wands* the Court set forth a non-exhaustive list of factors to be considered in determining whether undue experimentation would be involved in making and/or using the claimed invention. These factors include, but are not limited to:

- the breadth of the claims;
    - In the instant case, the claims refer to a method of selecting pulse lengths.
- the nature of the invention and state of the prior art;
    - In the instant case, the nature of the invention, i.e. pulse voltammetry/detection is well known in the art as shown in Lewandowski et al. (US 4,897,162, see entire document) and Henkens et al. (US 6,391,558 B1, see col. 37-38).
- the level of one of ordinary skill and the level of predictability in the art;
    - Selecting pulse lengths in known as shown in Bindra et al. (Anal. Chem. 1989, 61 2566-2570, see col. 1 on page 256).
- the amount of direction provided by the inventor and the quantity of experimentation needed to make or use the invention based on the content of the disclosure; and
    - In the instance case, the amount of direction provided by the inventor does not provide one skilled in the art the ability to arrive

at a specific pulse length or provide one skilled in the art with a method by which a pulse length is selected. In the instant case, it is not clear from the specification how pulse lengths are chosen which is what is being claimed. In section [0056] of applicant's PG Pub Document it appears that applicant has "set" the pulse lengths at times .25 and .75 seconds and has not provided clear criteria as to how these variables were arrived at which is the crux of claim 1. Additionally, with regard to figures 5 and 6, applicant notes that a measurement is being taken over a 10 second time period; however, it is not clear what these time periods represent. Are they the time of the measurement/relaxation phase? In the specification at section 00664 it refers to the time period as the first 10 seconds of measurement, but also notes other times such as .25 and 4.75 seconds.

- In addition, section 0074 notes that the pulse length, the repetition rate and the level of the potential can be predetermined which would not lead one to a method of selecting a pulse length if it is already determined.
- Additionally, with regard to figures 5 and 6, numerals 51-54 and 61-64 are the results of different relaxation phase durations. There is no indication of which one is preferred or as to how one skilled in the art would select an appropriate relaxation phase duration. No

clear criterion is noted in the specification to enable one skilled in the art to make a choice as to the appropriate pulse length or time.

- the existence of working examples;
    - Applicant provides graphs (figures 5 and 6) as noted above, but does not detail/explain which relax time (numerals 51-54, 61-64) is better or how to select which relax time over another to arrive at a method of selecting a pulse length.
    - It does not appear that there are any working examples that specifically explain how one is to arrive at or the criteria required to select a pulse length.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 1 and claims 2-10, 21-25 and 28, which depend from claim 1, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the following language; "relatively small" capacitive current; "towards the end" of the pulse; and "reversible to the greatest possible extent". These phrases are vague and confusing and do not provide guidance as to the criteria necessary for the claimed invention. For example, does "towards the end" refer to immediately after the pulse is applied, 10 seconds after the pulse is applied, etc.

5. Claim 3 is rejected under 35 U.S.C. 112, second paragraph. Claim 3 recites the limitation "when measuring oxidation currents" in line 2 and "in front of the electrode" in line 4. There is insufficient antecedent basis for these limitations in the claim.

6. Claim 4 is rejected under 35 U.S.C. 112, second paragraph. Claim 4 recites the limitation "measuring reduction currents" in line 2, "in front of the electrode" in line 4, and "pulsed redox-cycling" in line 4. There is insufficient antecedent basis for these limitations in the claim.

7. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 recites the following language "an adequate". This phrase is vague and confusing and does not provide guidance as to the criteria necessary for the claimed invention.

8. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 recites the following language "considerably longer". This phrase is vague and confusing and does not provide guidance as to the criteria necessary for the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-4 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Gunasingham et al. (J. Electroanal. Chem. 287, 1990, 349-362).

Regarding claims 1, 2 and 28, Gunasingham et al. teach a method for pulsed amperometric detection of the concentration of a mediator (TTF) in a biological system (page 350) in which the potential on the working electrode is pulsed by a potentiostat (page 351) such that the measurement and relaxation phases alternate (see figure 1, page 351). The phases being selected such that the duration of the measurement phase (PD) is chosen such that, towards the end of the pulse, the capacitive current is small in comparison to the Faraday current (page 353, "Effect of pulse duration"). A relaxation phase as shown in figure 1 so that the concentration gradient is relaxed is seen in figure 4. Thus the excess positively charged TTF that is not consumed will be reduced back to neutral TTF at the electrode surface and be available by the next oxidation pulse (page 354 "Effect of clock time").

Regarding claims 3 and 4, Gunashingham et al. teach measuring oxidation currents (see figure 3) and has a reduction potential wherein the excess charged TTF that is not consumed will be reduced back to the neutral TTF at the electrode surface so that it will be available by the next oxidation pulse (page 354, pulsed redox cycling).

10. Claims 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Bindra et al. (Anal. Chem. 1989, 61 2566-2570, see col. 1 on page 256).

Regarding claims 26 and 27, Bindra et al. teach a biosensor comprising a means, i.e. PARC Model 400, for pulsing the potential of the working electrode between measuring and relaxation phases (see col. 1 on page 2567 under Apparatus and Nafion Coating headings). If the PARC is designed to apply a repeating sequence of three applied potentials (i.e. measure, oxidize, and reactivate) according to a specified timing, this would read on the means for selecting measuring phase pulse length and relaxation pulse length as the device is programmable. Finally, Bindra et al. teach the use of a Princeton Applied Research Model 400 electrochemical detector and a Shimadzu CR 4A integrator which is used to process the detector output.

11. Claims 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Henkens et al. (US 6,391,558 B1).

Regarding claims 26 and 27, Henkens et al. teach pulsed electrochemical detection in which there is a means for applying a series of pulses which itself can be programmed by a user as to what pulse lengths, times, and strengths (i.e. means for selecting and multiplexed potentiostat) and a detection/measuring means (i.e. electrochemical pulse analyzer)(col. 5, lines 1-20; col. 6, lines 15-35).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 5, 10 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gunasingham et al. (J. Electroanal. Chem. 287, 1990, 349-362), as applied above to claims 1 and 3, in view of Bindra et al. (Anal. Chem. 1989, 61 2566-2570).

Regarding claim 5, 10 and 21, Gunasingham et al. teach a method for selecting pulse lengths, but does not specifically teach the claimed repetition rate or phase times.

Bindra et al. teach pulsed amperometric detection and that it is known in the art to utilize current-potential response curves for the analyte of interest in order to select the appropriate pulse lengths and repetition rates (page 2567, col. 1, "Nafion Coating")

It is noted that applicant has provided numerous dependent claims related to the phase lengths. Additionally, applicant's specification at section 0074 notes that the pulse length, the repetition rate and the level of the potential can be predetermined. In particular, the pulse lengths of the measuring phases and the relaxation phases can be set separately and be of different lengths. The potentials can also be of different magnitudes.

Since no specific guidance or criticality is provided as to the phase lengths or repetition rates are noted, it is not inventive to discover the optimum or workable ranges by routine experimentation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The discovery of an optimum value of a known result effective variable, without producing any new or unexpected result, is within the ambit of a person of ordinary skill

in the art. See *In re Boesch*, 205 USPQ 215 (CCPA 1980)(see MPEP § 2144.05, II). Therefore, it would have been obvious to a person of ordinary skill in the art to select the appropriate repetition rates and phase lengths to facilitate effective concentration detection using pulsed amperometric detection.

Additionally, it would have been obvious to one skilled in the art to utilize a predetermined current-potential response curve to select a repetition rate and phase length in Gunasingham et al. appropriate for the desired detection as taught by Bindra et al. because these curves are known and utilized in the art.

13. Claims 6-8 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gunasingham et al. (J. Electroanal. Chem. 287, 1990, 349-362), as applied above to claims 1, 3, and 4, in view of Buck et al. (WO 01/21827).

Regarding claims 6-8 and 22-24, Gunasingham et al. teach a method for selecting pulse lengths which can be rectangular (see figure 1), but does not specifically teach the claimed relaxation and measuring phases.

Buck et al. teach a method of utilizing pulsed amperometric detection. Specifically, figures 6-9 show that different pulse lengths can be selected. Figure 6, shows a pulse sequence in which two pulses of oxidative potential of different duration are applied to the sensor, interspersed with recovery intervals with reducing potential. By comparing the current profile from the first pulse with that from the second, information on the rate of enzymatic turnover of the substrate, and the rate of electron diffusion within the sensor may be obtained. Between the oxidative potential

applications, the reducing potential ensures that all of the mediator is returned to its initial state prior to the application of the next oxidizing potential. Figure 7 shows a sequence in which the duration of the intervals between the pulses is changed. By comparing the current observed from the second pulse to that from the first, information on the recovery time of the sensor can be gained. The recovery time yields information not only on analyte concentration, but also on diffusion into the hydrophilic matrix. Measuring the rest potential of the sensor between the potentiostatic pulses also provides information on the sensor recovery. Figures 8 and 9 demonstrate measurement protocols, which combine changes in the pulse interval with changes in the pulse width. The controller can select from a variety of sequences and durations of amperometric measurement intervals and recovery intervals to determine not only the analyte concentration, but also probe the condition of the sensor for enzyme activity, diffusion of substrate and mediator within the sensor, and diffusion of substrate into the sensor (see pages 13-14). In summary, Buck et al. teach that one skilled in the art would select the appropriate pulse length or curve profile in order to obtain the desired information be it recovery time, condition of the sensor, enzyme activity, or rate of reaction.

It is noted that applicant has provided numerous dependent claims related to the variation in pulse length and shape. Additionally, applicant's specification at section 0074 notes that the pulse length, the repetition rate and the level of the potential can be predetermined. In particular, the pulse lengths of the measuring phases and the

relaxation phases can be set separately and be of different lengths. The potentials can also be of different magnitudes.

Since no specific guidance or criticality is provided as to the curve type or phase durations and no unexpected results are noted, it is not inventive to discover the optimum or workable ranges by routine experimentation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The discovery of an optimum value of a known result effective variable, without producing any new or unexpected result, is within the ambit of a person of ordinary skill in the art. See *In re Boesch*, 205 USPQ 215 (CCPA 1980)(see MPEP § 2144.05, II). Therefore, it would have been obvious to a person of ordinary skill in the art to select the appropriate pulse course and phase length to facilitate effective concentration detection using pulsed amperometric detection.

Additionally, it would have been obvious to one skilled in the art to select a pulse length and curve in Gunasingham et al. appropriate for the desired detection as taught by Buck et al. because selecting these parameters will lead to the desired detection be it recovery time, condition of the sensor, enzyme activity, or rate of reaction.

14. Claims 9 and 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gunasingham et al. (J. Electroanal. Chem. 287, 1990, 349-362) and Buck et al. (WO 01/21827), as applied above to claim 8, in view of Bindra et al. (Anal. Chem. 1989, 61 2566-2570).

Regarding claims 9 and 25, Gunasingham et al. teach a method for selecting pulse lengths, but does not specifically teach the claimed repetition rate or phase times.

Bindra et al. teach pulsed amperometric detection and that it is known in the art to utilize current-potential response curves for the analyte of interest in order to select the appropriate pulse lengths and repetition rates (page 2567, col. 1, "Nafion Coating")

It is noted that applicant has provided numerous dependent claims related to the phase lengths. Additionally, applicant's specification at section 0074 notes that the pulse length, the repetition rate and the level of the potential can be predetermined. In particular, the pulse lengths of the measuring phases and the relaxation phases can be set separately and be of different lengths. The potentials can also be of different magnitudes.

Since no specific guidance or criticality is provided as to the phase lengths or repetition rates are noted, it is not inventive to discover the optimum or workable ranges by routine experimentation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The discovery of an optimum value of a known result effective variable, without producing any new or unexpected result, is within the ambit of a person of ordinary skill in the art. See *In re Boesch*, 205 USPQ 215 (CCPA 1980)(see MPEP § 2144.05, II). Therefore, it would have been obvious to a person of ordinary skill in the art to select

the appropriate repetition rates and phase lengths to facilitate effective concentration detection using pulsed amperometric detection.

Additionally, it would have been obvious to one skilled in the art to utilize a predetermined current-potential response curve to select a repetition rate and phase length in Gunasingham et al. appropriate for the desired detection as taught by Bindra et al. because these curves are known and utilized in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dieterle whose telephone number is (571) 270-7872. The examiner can normally be reached on Monday thru Thursday, 9am to 4pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alexa Neckel can be reached on (571) 272-1446. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JMD
9/3/10

/Alexa D. Neckel/
Supervisory Patent Examiner, Art Unit 1795